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EXAMINER	
GUDIBANDE, SATYANARAYAN R	

ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
11/26/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/584,449	PAI ET AL.	
	Examiner	Art Unit	
	SATYANARAYANA R. GUDIBANDE	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7 and 9-23* is/are pending in the application.

4a) Of the above claim(s) *5 and 20-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 7, 9-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Bib Data sheet*.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I (claims 1-19) and election of species in the in the following table,

No.	Species	Election
1.	1-5, 9, 10, 20 & 22 Water-soluble drug	Insulin
2.	1, 6, 7, 9, 10 & 20 Counter-ion substance	Sodium salt of C8-C18 fatty acid
3.	1, 11, 12 & 20 Lipid	monoglyceride
4.	1, 13 & 20 Polymer	Methacrylic acid copolymer
5.	17 & 18 Cryoprotecting agent	mannitol
6.	1, 14, & 20 Emulsifier	Polyoxyethylene polyoxypropylene copolymer
7.	22 pH adjusting agent	Citric acid

reply filed on 2/27/08 was acknowledged and the traversal arguments were answered in the office action dated 4/23/08.

Applicant's amendment to claims in the response filed on 8/20/08 has been acknowledged.

Claims 1-5, 7, 9-23 are pending.

Claim 5 remains withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/27/08. Art was found on the elected species of insulin and has been applied in the rejections below. Hence claim 5 which is drawn to drug which is one charged in water has been withdrawn from further consideration.

Claims 20-23 remains withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/7/08.

Claims 6 and 8 have been canceled.

Claims 1-19 are examined on the merit.

Any objections and/or rejections made in the office action dated 4/23/08 and not specifically mentioned here are considered withdrawn.

Priority

A corrected copy of the Bib data sheet has been attached granting foreign priority.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim1-3, 9-11, 15 and 17 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement as stated in the office action dated 4/23/08 and as reiterated below. The rejection has been modified to reflect the amendments made to the claims 1, 7, 9-11, 16 and 19. Response to applicant's arguments appear at the end of the reiterated rejection. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant invention applicants claim a orally administrable composition containing nanoparticle size of 500 nm or less comprising 0.1-30% weight% complex of a water soluble drug and a counter-ion substance wherein said counter-ion substance is an anionic compound selected from the group consisting of sodium salt of C_{8-18} fatty acid, sodium salt of bile acid, sodium alginate, and sodium carboxymethylcellulose, or a cationic compound selected from the group consisting of carnitine salt, benzalkonium chloride and cetrimide, 0.5-80 weight% of a lipid, 0.5-80 weight% of a polymer, and 1-80 weight% of an emulsifier, wherein the weight ratio of said lipid and said polymer is in the range of 1:0.05-3.

Factors to be considered in making the determination as to whether one skilled in the art would recognize that the applicant was in possession of the claimed invention as a whole at the time of filing include:

a. Actual reduction to practice;
b. Disclosure of drawings or structural chemical formulas;
c. Sufficient relevant identifying characteristics such as:
    i. Complete structure,
    ii. Partial structure,
    iii. Physical and/or chemical properties or
    iv. Functional characteristics when coupled with a known or disclosed correlation between function and structure;
d. Method of making the claimed invention;
e. Level of skill and knowledge in the art and
f. Predictability in the art.

While all of these factors are considered, a sufficient number for a *prima facie* case are discussed below.

The claim 1 as recited encompasses any and all charged water-soluble drugs without disclosing any structural or functional attributes of the drugs that constitute a

'water soluble drug'. There are many classes of molecules that fit the generic definition of water soluble molecules, such as peptides, nucleic acids, amino acids, nucleotides, sugars, etc., in which some species of these classes are water soluble and some or not depending on the substitutions or derivatization of either the monomers or the polymers. Thus the genus of water soluble molecules encompasses a very large genera of different classes and subclasses of compounds of known and unknown compounds with a vast array of built in structural and functional complexity. Mere recitation of "a water soluble drug" does not provide written description to the claims as recited. The specification only discloses, insulin and ceftriaxone as drugs in specific examples as water soluble drugs. The claim as recited and the specification as disclosed do not provide a proper definition for the phrase "water soluble drug" and supplement the definition with representative examples to support the scope of the claim as recited.

Claim 1 also recites other components such as "lipids", "polymer" and "emulsifier". The genus of lipids encompasses multitude of compound that further belongs to several classes of compounds. The term "polymer" and "emulsifier" encompasses any and all known and unknown classes and genera of compounds that are polymers and surfactants. The instant specification with only a few representative examples which are again genera and subgenera of each of these very broad classes of compounds does not adequately support the vast breadth of the claims as recited.

Therefore, the claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Response to Arguments

1. Applicants argue that the technical feature of the present invention is the reaction of the charged water-soluble drug with the counter-ion substance, and further with lipid, polymers, and emulsifiers, it does not necessarily rest on the specific kinds of water-soluble drug, lipid, polymer and emulsifier. Applicants further state that the kind of lipids are disclosed on page 13, lines 1-5; kind of polymers on page 13, lines 7-15 and the kind of emulsifiers on page 14, lines 8-19.

Applicant's arguments filed 8/20/08 have been fully considered but they are not persuasive. Applicants' state that the instant claim that recites a complex of a charged water-soluble drug with a counter-ion substance on page 10 of the reply filed on 8/20/08 provide written description to the instant invention and "**it does not necessarily rest on the specific kinds of water-soluble drug, lipid, polymer and emulsifier**". On the contrary, on page 13, in the reply to anticipation rejection over EP'566, applicants' argue that the prior art reference EP'566 that discloses nanocomposition comprising an active ingredient (drug) which is a hydrophilic or hydrophobic with cationic and anionic lipids and/or polymers does not read on the instant claims. This clearly illustrates the office's position that the instant claims lack written description showing that any charged hydrophilic drug (water soluble) along with a counter-ion reads on instant claims.

Hence, the written description under 35 USC 112 is appropriate and is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7, 11-15 and 17-19 remain rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 771 566 A1 of Fernandez as stated in the office action dated 4/23/08 and as reiterated below. The rejection has been modified to reflect the amendments made to the claims 1, 7, 9-11, 16 and 19. Response to applicant's arguments appear at the end of the reiterated rejection.

In the instant invention applicants claim a orally administrable composition containing nanoparticle size of 500 nm or less comprising 0.1-30% weight% complex of a water soluble drug and a counter-ion substance wherein said counter-ion substance is an anionic compound selected from the group consisting of sodium salt of C_{8-18} fatty acid, sodium salt of bile acid, sodium alginate, and sodium carboxymethylcellulose, or a cationic compound selected from the group consisting of carnitine salt, benzalkonium chloride and cetrimide, 0.5-80 weight% of a lipid, 0.5-80 weight% of a polymer, and 1-80 weight% of an emulsifier, wherein the weight ratio of said lipid and said polymer is in the range of 1:0.05-3.

Fernandez teaches a colloidal system comprising nanoparticles, nano capsules and nano emulsions for oral administrations of medicaments (Abstract). The reference discloses negatively charged phospholipid (lecithin), positively charged polysaccharide chitosan, polyoxyethylenenated oils (Migliol), polyepsiloncaprolactone as polymer and

drugs such as cyclosporin A, indomethicin, metipropanol and thiopental are as active drugs are used in the nanocomposition (page 3, lines 10-28, and example 1 on page 5). The reference also teaches the invention can be used to incorporate one or more active ingredients of a hydrophilic or lipophilic character (page 3, lines 21-22). The particle size disclosed in tables 1, 2 and 4 are <500 nm. The %weight of lecithin (a negatively charged molecule) is 1% and % weight of chitosan (a positively charged molecule) is 1% (Example 1) and the % weight of complex of an active molecule associated with the charged molecules is at least 1% (is within the range of 0.1-30% of instant invention), the weight % of lipid (lecithin) is 1% (is within the range of 0.5-80% of instant invention), the weight % of polymer (polyepsiloncaprolactone) is 1% (is within the range of 0.5-80% of instant invention), the weight % of emulsifier (Migliol) is 1.5% (in examples 2 and 3 is within the range of 1-80% of instant invention) and the weight ratio of lipid and polymer in the cited reference is 1 (is within the range of 1:0.05-3). This meets the limitations of claims 1, 11 and 19. Since the drug is encapsulated in the nano particle or nano capsule, it is inherent that 70% or more is entrapped in the nano particles. Hence meets the limitation of claim 2. The lecithin is phospholipid of glycerol origin and a fatty acid (C8-C18) and hence meets the limitations of instant claims 1, 7, 12 and 14. The cited reference of Fernandez also discloses chitosan (Example 1) and hence meets the limitation of claim 13. The cited reference of Fernandez also discloses acetone (25 mL) as a solubilizing agent (page 5, line 38) and hence meets the limitation of instant claim 15. The cited reference of Fernandez also discloses glucose as cryoprotective agent (page 3, lines 17-and 18) and hence meets the limitation of claim 18. Thus the cited reference of Fernandez anticipates the instant claims 1, 2, 7, 12-14 and 17-19.

Response to Arguments

Applicants argue that EP'566 does not suggest or disclose the instantly claimed subject matter:

1. First, the present invention is applied to the charged water-soluble drug only, whereas EP '566 is applied to any kind of drugs such as charged and/or uncharged water-soluble and lipid- soluble drugs (see: the descriptions of EP '566, e.g. The systems can be formulated in different ways to incorporate in their structure one or more active ingredients of a hydrophilic or lipophilic character.).

2. Second, EP '566 does not teach or suggest the counter-ion substance as recited in the present claims. Such counter-ion substance reacts with the charged water-soluble drug to form a complex. Accordingly, a skilled artisan would have had no reason or motivation to consider EP '566 for preparing formulations for charged water-soluble drugs, wherein the drugs are not exposed to external chemical environment, e.g. pH or digestive enzymes, by entrapping them with lipids or polymers with high affinity with biological membranes.

3. Third, EP '566 relates to a process for the preparation of pharmaceutical compositions in the form of colloidal particles, and the colloidal particles are coated with a film made up Of combination of cationic aminopolysaccharide and a phospholipid negatively charged. It relies on the incorporation of lecithin, as a lipophilic surfactant, in the dispersed phase and of the chitosan, as a hydrophilic suspending, in the continuous aqueous phase. EP '566 provides colloidal particles with a positive charge by reacting lecithin and chitosan (see: page 2 of EP '566). In other words, the positively charged chitosan interacts with the negatively charged phospholipids to form a positively charged

particle at the interface of the colloidal system. EP '566 also discloses that the inner structure of the systems is a) a reservoir system consisting of a oily surrounded or not by a polymer wall, and b) a matrix system consisting of solid particles containing none or little amounts of oil entrapped (see: page 3 of EP '566).

In contrast, in the present invention, the charged water-soluble drug (=active ingredients) reacts with the counter-ion substance to form a complex, and then the neutralized complex is entrapped by the hydrophobic bonding between the lipid and polymer. When the lipid/polymer nanoparticles are dispersed in an aqueous solution, the emulsifier may stabilize the dispersion.

In summary, EP '566 does not teach or suggest that the charged drug and complex thereof with counter-ion substance by ionic bonding. EP '566 describes the positively charged colloidal particles by reacting positively charged chitosan with negatively charged lecithin, and the positively charged particles are totally different from the neutralized complex of the present invention. Also, the forming pattern of inner structure is different from that of the present invention as mentioned above.

Applicant's arguments filed 8/20/08 have been fully considered but they are not persuasive.

1. Applicants assertion that EP'566 discloses any kind of drugs charged and/or uncharged, water soluble and lipid soluble drugs, although true, it encompasses charged water soluble drugs as well. Moreover, the instant claim 1 is drawn to charged water soluble drugs in general and does not specifically identifies any drug compound in particular.

2. Applicant's argue that EP'566 does not teach the counter-ion substance as recited in the present claim that such counter-ion substance reacts with the charged water-soluble drug to form a complex is not persuasive. The claims are drawn to a composition **comprising** number of components such as charged water-soluble drug, counter-ion, lipid, polymer, etc. The interaction of charged molecules, charged water-soluble drug and the counter ion is basic. The disclosure in EP'566 that the composition comprises of drug (charged or uncharged and water or lipid soluble) and the presence of phosphatidic acid (phospholipid) (page 2, line 14), chitosan (a polymer) meets the limitations of the instant invention and has been well illustrated in the rejection above.

Applicant's further comment that "[A]ccordingly, a skilled artisan would have had no reason or motivation to consider EP '566 for preparing formulations for charged water-soluble drugs, wherein the drugs are not exposed to external chemical environment, e.g. pH or digestive enzymes, by entrapping them with lipids or polymers with high affinity with biological membranes" is misplaced. The instant claims does not recite any of the aforementioned limitations.

3. Applicants argue that the instant invention is distinct from that of EP'566 by stating that colloidal particles of EP'566 is charged compared to neutral particles of the instant invention. It should be noted that the claims as recited does not identify or define the nature of the lipids, emulsifiers or polymers incorporated in the instant invention that impart the neutrality to particles of the instant invention in claim 1.

Hence the anticipation rejection as stated above over EP'566 is proper and is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 7, 9-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 2004/043513 A2 of Shefer as stated in the office action dated 4/23/08 and as reiterated below. The rejection has been modified to reflect the amendments made to the claims 1, 3, 7, 9-11, 16 and 19. Response to applicant's arguments appear at the end of the reiterated rejection.

In the instant invention applicants claim a orally administrable composition containing nanoparticle size of 500 nm or less comprising 0.1-30% weight% complex of a water soluble drug and a counter-ion substance wherein said counter-ion substance is an anionic compound selected from the group consisting of sodium salt of C_{8-18} fatty acid, sodium salt of bile acid, sodium alginate, and sodium carboxymethylcellulose, or a

cationic compound selected from the group consisting of carnitine salt, benzalkonium chloride and cetrimide, 0.5-80 weight% of a lipid, 0.5-80 weight% of a polymer, and 1-80 weight% of an emulsifier, wherein the weight ratio of said lipid and said polymer is in the range of 1:0.05-3.

Claim 33 of the cited reference of Shefer discloses the drug insulin as the active ingredient which is a water soluble drug and the drug is encapsulated in a hydrophobic nanosphere as recited in the claim 85 of Shefer. The claim 25 of the cited reference discloses a cationic surface active agents consisting of calcium sulfate, sodium lauryl sulfate, etc., that are salts and salts of detergents. Claim 8 of the Shefer discloses the elected species of lipid, i.e., monoglyceride. Claim 16 of the Shefer discloses polymers such as methacrylate and methacrylic acid. Claim 23 of Shefer discloses ethoxylated/propoxylated block polymers and hence reads on the elected species of emulsifier polyoxyethylene polyoxypropylene copolymer. Claim 82 of Shefer discloses the size of the nanosphere as 2-30 microns and hence meets the limitation of the nanoparticle range of the instant application. Hence this meets the limitations of instant claims 1, 2, 4, 6, 7, 12, 13 and 15. Shefer also discloses that the invention addresses the matrix composition for controlling the lag time and release rate of pharmaceutical and other active ingredients onto certain regions of the gastrointestinal tract including stomach and small intestine (page 8, lines 13-20). This reads on instant claim 3 wherein the 80% of the drug is retained in the particles when the composition is mixed with pancreatin. Shefer discloses benzylalkonium chloride (claim 24) as surface active material and hence meets the limitation of instant claim 8. Claim 42 of Shefer discloses that the composition comprises of 0 to 30% by weight of surface active agents and 1 to

50% by weight of active ingredients. This meets the limitations of instant 9 and 10 since the disclosed %wt of active ingredients and surface active agents encompass the recited range in the instant claims. Claim 8 of Shefer discloses the elected species monoglyceride and hence reads on instant claim 12. Claim 9 of the Shefer discloses the fatty acid derivatives selected from alcohol and hence reads on instant claim 16. Claim 16 of the Shefer also discloses polyethylene oxide (also known as polyethylene glycol) hence reads on instant claim and hence reads on instant claim 16. Claim 23 of Shefer discloses ethoxylated/propoxylated block polymers and hence reads on the elected species of emulsifier polyoxyethylene polyoxypropylene copolymer. Claim 15 of Shefer discloses the elected species of mannitol as water sensitive and hence reads on instant claims 17 and 18.

The reference of Shefer does not disclose range of percentages recited in claims 1, 3, 11, 15 and 17.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of taught by Shefer to arrive at the instant invention. Because, according to MPEP Section 2144.05, Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The skilled artisan would have been motivated to do because, "[T]he normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the

optimum combination of percentages" (MPEP 2144.05). There would have been a reasonable expectation of success, given the fact that Shefer had used the method to successfully incorporate insulin drug in to nanosphere.

Thus, the invention as a whole would have been prima facie obvious to one skilled in the art the time the invention was made.

Response to Arguments

Applicants argue that "WO'513 provide a controlled release system including a matrix composition for controlling the lag time and release rate of active ingredients. The matrix composition comprises a wax material, fat material, water sensitive material, and surface active material.

In contrast, the purpose of the present invention is to provide orally administrable nanoparticle compositions having an enhanced entrapping rate of water-soluble drugs within the nanoparticle composed of lipids and polymers, and the nanoparticle composition comprised a water-soluble drug, counter-ion substance, lipid, polymer and emulsifier.

Comparing the present invention with WO '513, the purposes and components of both inventions are different from each other. **More specifically, the wax material working as a controlling material of the erosion rate, mechanical properties, and physical integrity of the matrix is an essential component of WO '513 whereas the nanoparticle composition of the present invention lacks the wax material (emphasis added by the office).** Thus, the essential components of the present invention are

different from those of WO '513, and WO '513 does not mention or suggest any composition comprising the essential components of the present invention.

Applicant's arguments filed 8/20/08 have been fully considered but they are not persuasive. It should be noted that the instant invention is drawn to a composition with a transition phrase "**comprising**" to describe the invention. The use of the term "comprising" does not preclude additional agents in the composition and in this case the presence of wax in the Shefer composition. Applicant's statement that "WO '513 does not mention or suggest any composition comprising the essential components of the present invention" is not persuasive. As illustrated in the rejection above, the invention disclosed by Shefer discloses many of the components of the instant invention in the insulin encapsulated nanosphere composition.

Hence the obviousness rejection over Shefer is proper and is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Satyanarayana R Gudibande/
Examiner, Art Unit 1654

/Andrew D Kosar/
Primary Examiner, Art Unit 1654